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REMARKS

This amendment is responsive to the Office Action of July 3, 2001. Reconsideration of claims 1-22 is respectfully requested.

The Office Action

Claim 3 stands rejected under 35 U.S.C. § 112 second paragraph, as being indefinite.

Claims 1-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Minerovic, et al. (U.S. Patent No. 5,997,814) in view of Malchesky, et al. (U.S. Patent No. 5,518,927).

35 U.S.C. § 112

The applicants have amended claim 3 to call for an inner, second cup including a second peripheral wall, the second peripheral wall having a detachable base. This is supported by the specification at page 11, lines 20-32. It is submitted that all claims now comply fully with the requirements of 35 U.S.C. § 112.

The Present Application

The present application is directed to a single use package for holding a powdered composition. The applicants have found that even when the appropriate dosage for a sterilization cycle has been metered into a package, the decontaminant solution is occasionally below the desired concentration. This may occur, for example, if the powdered ingredients have degraded over time or are not properly released into the solution. Although the packaging includes an expiration date and storage instructions, packages that have been stored too long or under improper conditions are sometimes used. Hemoglobin reacts rapidly with oxidants lowering the concentration of oxidizing sterilants in solution. Items with an abnormally heavy blood load can react so aggressively with the sterilant that the minimum

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acceptable concentration is not reached in a single processing cycle.

An indicator is located on a porous portion of the package and exhibits a detectable change on exposure to the decontaminant in the solution. The indicator provides assurance that the decontaminant solution reached the appropriate concentration for sterilization, high level disinfection, or the like. A lack of color change of the indicator or a lesser color change than expected can be used as an indication that the processing cycle was conducted with a solution below an effective concentration.

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### The References of Record

The Minerovic, et al. patent is directed to a one-use, two-compartment cup for holding dry reagents. A first reagent is held in a cup formed from a porous material. A second reagent is held separately from the first reagent in an outer cup. A water permeable top cover seals the outer cup and traps the reagents in their respective cups. A detachable base wall 58 is formed at the base of the outer cup.

The Malchesky, et al. patent is directed to a lifespan indicator for a multiple use instrument. The indicator includes a label 10 laminated between two layers of pigment impregnated plastic 14. The pigment changes color when exposed, over multiple cycles, to a sterilization fluid. As the pigment is exposed to the sterilant, the pigment fades, allowing a warning indicia 12 on the label 10 to be read. The pigment or the impregnating are formulated or selected such that the color change occurs after a preselected number of processing cycles. The label is attached to a medical instrument and remains on the instrument through repeated sterilization cycles. It is only after exposure to the selected number of cycles the color change occurs. For example, the instrument may undergo forty cycles before color change is observed (col. 3, lines 65-67), although fewer cycles may be counted (col. 4, lines 5-7). When the color change eventually occurs, the instrument is typically examined and repaired or simply discarded.

### The Claims Distinguish Patentably Over the References of Record

Claim 1 calls for a single-use package for holding a powdered composition which forms a solution of an anti-microbial decontaminant when mixed with water. The package includes an indicator which exhibits a detectable change on exposure to the decontaminant in the solution. Such an indicator provides the operation with an immediate

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indication whether the sterilization or disinfection cycle was successful.

The references of record, alone or in combination, do not disclose or fairly suggest such a single-use package with an indicator of successful operation. As the Examiner acknowledges, Minerovic, et al. does not teach using an indicator which exhibits a detectable change on exposure to the decontaminant in the solution. Moreover, Minerovic, et al. provides no motivation for including such an indicator. As indicated in the background section of the Minerovic, et al. patent, a "two-compartment cup ensures sterilization with a reproducible, pre-measured dose of reagents" (col. 2, lines 1-3). There is no suggestion in the Minerovic, et al. patent that the measured dose may not always ensure sterilization. The present inventors have found, however, that sterilization conditions are not always achieved, for example, if the reagents have degraded over time.

The indicator of Malchesky, et al. is a counter. The Malchesky indicator counts the number of times that an instrument has been processed. There is no reason to count the number of times the Minerovic cup has been used -- it is always discarded after its first use.

The Malchesky count indicator is used on devices undergoing multiple sterilization cycles. The indicator of Malchesky, et al. is contained by layers plastic 14, which prevent the indicator from fading until the instrument, with the label attached, has undergone multiple sterilization cycles. For the indicator to fade after only a single cycle would defeat the invention of Malchesky, et al. since its purpose is to provide an indication that the instrument has undergone a large number of cycles and may thus have suffered sufficient damage that it needs to be repaired or replaced. There is no suggestion of using Malchesky's indicator only once -- there is no motivation to use a count indicator on an item that is to be discarded after only a single sterilization cycle. Thus, Malchesky, et al. teaches against using the indicator on a package which is only

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useable one time. Accordingly, there is no motivation for combining the references of Minerovic, et al. and Malchesky, et al.

Moreover, combining the two references would not arrive at the presently claimed invention. The indicator of Malchesky, et al., if attached to the package of Minerovic, et al. would not be expected to exhibit a detectable change on exposure to the decontaminant in the solution during a single cycle, since it is not designed to change color until it has been exposed to multiple cycles.

Accordingly, it is submitted that claim 1 and claims 2-7, 9-14, 16-18, and 22 dependent thereon, differ patentably and unobviously over the references of record.

Claim 8 focuses on the location of the indicator on a single use package for holding a dry composition which forms an anti-microbial solution when mixed with water. The package includes a side wall and a bottom wall across a lower portion of the sidewall. A top cover defines a porous portion which is impermeable to the dry composition but is permeable to water and to the solution. An indicator on the top cover exhibits a detectable change on exposure to the anti-microbial solution.

None of the references of record, alone or in combination, discloses or fairly suggests such a single-use package with an indicator on a top cover. As discussed for claim 1, Malchesky, et al. teaches against using an indicator on a package which is intended for one time use. Moreover, the Malchesky indicators are mounted on solid plastic materials, not porous. Minerovic, et al. provides no motivation for using an indicator on a single use package. Thus, there is no motivation for combining the references of Minerovic, et al. and Malchesky, et al., much less this advantageous placement of the indicator.

Accordingly, it is submitted that claim 8 differs patentably and unobviously over the references of record.

Claim 15 calls for an indicator which exhibits a detectable color change when exposed to a preselected

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minimum concentration of the decontaminant for a preselected minimum period of time to indicate the formulation of an anti-microbial solution capable of effecting anti-microbial decontamination.

None of the references of record, alone or in combination, discloses or fairly suggests a concentration and time indicator.

The Minerovic, et al. patent provides no motivation for employing any indicator. The indicator of Malchesky, et al. is a counter. It does not indicate whether the formulation of an anti-microbial solution in any one cycle was capable of effecting anti-microbial decontamination.

Accordingly, it is submitted that claim 15 differs patentably and unobviously over the references of record.

Claim 19 calls for an anti-microbial system including a well for receiving a single use package. A porous portion is permeable to an anti-microbial solution formed from an anti-microbial concentrate and water. An indicator on the porous portion exhibits a detectable change on exposure to a decontaminant in the solution. A source of water and a chamber are provided. Recirculating anti-microbial solution passes over the indicator.

The references of record do not fairly suggest such a system. The Minerovic, et al. patent provides no motivation for employing an a indicator in the sterilization system shown in Figure 1 of the patent. It is assumed that the reproducible, premeasured dose will ensure sterilization. Malchesky, et al. does not suggest putting an indicator on a single use package. Rather, the indicator is placed on an instrument which is reused multiple times.

Accordingly, it is submitted that claim 19 differs patentably and unobviously over the references of record.

Claim 20 calls for a package for releasing an anti-microbial composition into a flowing liquid. A layer of porous material spans one of first and second openings such that the liquid flows through the porous material

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layer. An indicator on the porous material layer changes color in response to contact with the anti-microbial solution, a degree of color change varying in accordance with (i) a concentration of an anti-microbial agent in the solution contacting the indicator, and (ii) a duration that the solution contacts the indicator such that the degree of color change of the indicator is indicative of duration of contact and the concentration of the anti-microbial agent in the contacting solution.

The references of record do not fairly suggest such a package. The indicator of Malchesky, et al. is placed on an instrument to count the multiple number of times it is reused. Malchesky, et al. does not suggest an indicator which is indicative of duration and concentration of the contacting solution.

Accordingly, it is submitted that claim 20 differs patentably and unobviously over the references of record.

Claim 21 calls for a method including flowing water through a cartridge containing a composition to form a decontaminant solution from the composition and the water, the cartridge including a porous region impregnated with an indicator. The indicator exhibits a preselected detectable change when contacted with a decontaminant solution and at a concentration of a decontaminant in the solution sufficient to effect decontamination of items.

The references of record do not suggest such a method. The indicator of Malchesky, et al. does not exhibit a detectable change when contacted with a decontaminant solution at a concentration of a decontaminant in the solution sufficient to effect decontamination of items. This would defeat the object of Malchesky, which is to provide an indicator which does not exhibit a detectable change until multiple sterilizations have taken place. If the indicator of Malchesky were used in the Minerovic, et al. system, it would provide a false reading every time, since a single sterilization cycle would not provide a color change.

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Accordingly, it is submitted that claim 21 distinguishes patentably and unobviously over the references of record.

The Minerovic, et al. Patent Can Be Removed  
As A Reference Against the Claims

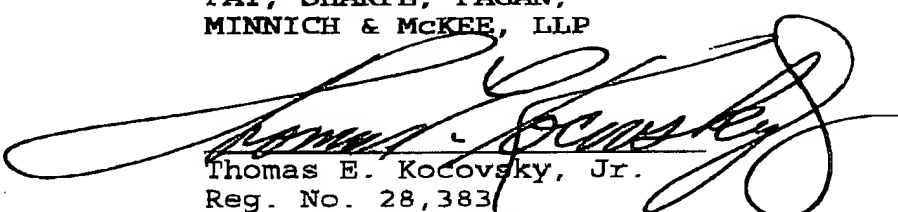
As the Examiner will appreciate, the Applicants can, under the provisions of 35 U.S.C. § 103(c), remove the Minerovic, et al. patent as a reference simply by filing a CPA or other continuation application.

CONCLUSION

For the reasons set forth above, it is submitted that claims 1-22 distinguish patentably and unobviously over the references of record. An early allowance of all claims is earnestly solicited.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this AMENDMENT B in connection with U.S. Patent Application Serial No. 09/314,497 is being transmitted by telefacsimile to the U.S. Patent and Trademark Office, Attention: Examiner M. CHORBAJI, Group Art Unit 1744, at Telephone No. (703) 305-7719 on this 6<sup>th</sup> day of September, 2001.

By: Hilary McNulty



Application Serial No. 9/314.497  
Filed May 19, 1999

VERSION OF CLAIMS WITH MARKINGS TO SHOW CHANGES MADE  
September 6, 2001

Please amend claim 3, as follows:

3. (Twice Amended) The package of claim 2,  
wherein the cartridge further includes:

an outer, first cup including a first peripheral  
wall with an opening at an end, the first peripheral wall  
5 being at least selectively water transmissive;

an inner, second cup including a second peripheral  
wall, the second peripheral wall having a detachable  
[portion] base, the first and second cups being configured  
such that the second peripheral wall abuts and is connected  
10 to the first cup adjacent the end of the first peripheral  
wall;

a top cover covering the openings in the first and  
second cups, such that the first compartment is defined in  
the first cup and the second compartment is defined in the  
15 second cup.